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Janssen Pharmaceuticals, Inc.
(f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.,
f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
Max Apel and Joan Apel, his wife v. Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development L.L.C., Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P., a/k/a Janssen, Pharmaceutica, Inc., Surinderjeet Sandhu, M.D., Preferred Behavioral Health of New Jersey, Inc., Maher Awad, M.D., and St. Barnabas Behavior Health Center, Kimball Medical Center, Kimball Northeast Short Term Care Unit, and Sireajuddin Ismail, M.D.	CASE NO. 274 CIVIL ACTION **ORDER**
Docket No. MID-L-010623-09-MT	

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); and the Court having ~~heard and~~ considered the moving papers, ~~any~~ opposition papers, ~~any~~ reply papers, ~~and the arguments of counsel,~~ and good cause having been shown;

IT IS on this 25th day of July, 2014,

ORDERED that Defendants' Motion for Summary Judgment be and hereby is granted for the reasons set forth in the court's memorandum of decision dated July 25, 2014

IT IS FURTHER ORDERED that Plaintiffs' Complaint be and hereby is dismissed with prejudice;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon Plaintiff~~ posted online for all counsel within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

ACTIVE/ 75762248.1

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
JESSICA R. MAYER, J.S.C.

MIDDLESEX COUNTY COURT HOUSE
P.O. Box 964
NEW BRUNSWICK, NJ 08903-0964

NOT FOR PUBLICATION WITHOUT THE APPROVAL OF THE COMMITTEE ON OPINIONS

Memorandum of Decision on Defendants' Motion for Summary Judgment

Max Apel, et al, v. Johnson & Johnson, et al, Docket No. MID-L-10623-09-MT
(In re: Risperdal®/Seroquel®/Zyprexa® Litigation, Case No. 274)

Plaintiffs: Brian W. McAlindin, Esq. and Adam S. Picinich, Esq., Bathgate, Wegener & Wolf, PC

Defendants: Thomas F. Campion, Esq., Heidi E. Hilgendorff, Esq., and Jodi Sydell Rosenzweig, Esq., Drinker Biddle & Reath LLP

Dated: July 25, 2014

Defendants Johnson & Johnson ("J & J") and Janssen Pharmaceuticals, Inc. ("Janssen") (collectively the "Defendants") move for summary judgment as to the claims asserted on behalf of plaintiffs Max and Joan Apel ("Plaintiffs") for failure to warn, negligence, breach of implied warranty, violation of the Consumer Fraud Act ("CFA"), and fraud. The court, in addressing Defendants' motion, reviewed the parties' filed submissions and the written arguments of counsel. The parties waived oral argument and submitted the matter to the court for resolution based upon the filed papers. The following memorandum of decision sets forth the court's disposition of Defendants' motion.

I. Background

Risperdal® (known in its generic form as "risperidone"), marketed by Janssen, "is a second generation or atypical antipsychotic agent, approved by the federal Food and Drug Administration ("FDA") in 1993."[1] On February 3, 2012, Plaintiffs filed a Third Amended Complaint[2] alleging that, "[a]s a direct and proximate use of using Risperdal [sic]. Plaintiff Max Apel developed tardive dyskinesia, tardive dystonia, repetitive purposeless involuntary motion, akathisia, decompensation and also developed and also experienced hyper-prolactinemia, [and] gynecomastia."[3] Mr. Apel has a significant history of diagnoses associated with multiple psychiatric disorders.[4] Mr. Apel has received various treatments for his mental illness from a variety of doctors over the last forty years.[5] Mr. Apel has been prescribed several medications for his mental illness, including Risperdal®.[6] Plaintiffs' claims center on Mr. Apel's ingestion of Risperdal® from March 2007 through May 2008.[7]

Risperdal® was first approved by the FDA in 1993. Since that date, the label has been revised several times.[8] The court shall focus on the 2006 Risperdal® label, which was "in effect in 2007 when Mr. Apel was prescribed Risperdal®."[9]

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[1] Brief in Support of Defendants' Motion for Summary Judgment ("Def. Brief") at 2.
[2] Plaintiffs' Complaint was filed on December 31, 2009.
[3] Plaintiffs' Third Amended Complaint and Jury Demand ("Third Amend. Comp.") at Count 2, Para. 17. Plaintiffs also produced a report written by Dr. William L. Manion, M.D., Ph.D. opining that, "Mr. Apel has developed Tardive Dyskinesia and Gynecomastia as a result of being prescribed Risperdal." Dr. Manion's report does not address the other conditions that Mr. Apel claims were caused by Risperdal®. Certification of Heidi E. Hilgendorff in Support of Defendants' Motion for Summary Judgment, dated June 12, 2014 ("Hilgendorff Cert."). Exhibit C at 4. The court notes that tardive dystonia is a subtype of tardive dyskinesia. U.S. National Library of Medicine National Institutes of Health, *Dystonia and Dyskinesia*, ABSTRACT, http://www.ncbi.nlm.nih.gov/pubmed/9443352 (last visited July 24, 2014).
[4] See Plaintiff Fact Sheet ("PFS"), Hilgendorff Cert. Exhibit B.
[5] Id.
[6] Id.
[7] Id. at 9.
[8] U.S. Food and Drug Administration, *Overview of Risperdal®*, http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Overview&DrugName=RISPERDAL (last visited July 14, 2014).
[9] Def. Brief at 2. Plaintiffs' Third Amended Complaint references the Risperdal® labeling and package inserts from 2001. Third Amend. Comp. at Count 2, Para. 7. The court is troubled by Plaintiffs' reference to the 2001 Risperdal®

II. Applicable Risperdal® Label Provisions

Under the "Warnings" section of the October 2006 Risperdal® label, the section for tardive dyskinesia states:

> **Tardive Dyskinesia**
>
> A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs. Although the prevalence of the syndrome appears to be highest among the elderly, especially elderly women, it is impossible to rely upon prevalence estimates to predict, at the inception of antipsychotic treatment, which patients are likely to develop the syndrome. Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown.
>
> The risk of developing tardive dyskinesia and the likelihood that it will become irreversible are believed to increase as the duration of treatment and the total cumulative dose of antipsychotic drugs administered to the patient increase. However, the syndrome can develop, although much less commonly, after relatively brief treatment periods at low doses.
>
> There is no known treatment for established cases of tardive dyskinesia, although the syndrome may remit, partially or completely, if antipsychotic treatment is withdrawn. Antipsychotic treatment, itself, however, may suppress (or partially suppress) the signs and symptoms of the syndrome and thereby mask the underlying process. The effect that symptomatic suppression has upon the long-term course of the syndrome is unknown.
>
> Given these considerations, RISPERDAL® (risperidone) should be prescribed in a manner that is most likely to minimize the occurrence of tardive dyskinesia. Chronic antipsychotic treatment should generally be reserved for patients who suffer from a chronic illness that: (1) is known to respond to antipsychotic drugs, and (2) for whom alternative, equally effective, but potentially less harmful treatments are not available or appropriate. In patients who do require chronic treatment, the smallest dose and the shortest duration of treatment producing a satisfactory clinical response should be sought. The need for continued treatment should be reassessed periodically.
>
> If signs and symptoms of tardive dyskinesia appear in a patient treated with RISPERDAL®, drug discontinuation should be considered. However, some

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label, as that was not the label in effect in 2007 when Mr. Apel was prescribed Risperdal®. Moreover, if Plaintiffs' claims were premised on the 2001 Risperdal® label, the claims would arguably be time barred since Plaintiffs' Complaint was first filed on Dec. 31, 2009. The court assumes this is an inadvertent error by Plaintiffs' counsel based on the Plaintiffs' certified responses set forth in the PFS.

patients may require treatment with RISPERDAL® despite the presence of the syndrome.[10]

Under the "Precautions" section of the October 2006 Risperdal® label, the section for hyperprolactinemia states:

> Hyperprolactinemia
> As with other drugs that antagonize dopamine D_2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration. Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents.
>
> Hyperprolactinemia may suppress hypothalamic GnRH, resulting in reduced pituitary gonadotropin secretion. This, in turn, may inhibit reproductive function by impairing gonadal steroidogenesis in both female and male patients. Galactorrhea, amenorrhea, gynecomastia, and impotence have been reported in patients receiving prolactin-elevating compounds. Long-standing hyperprolactinemia when associated with hypogonadism may lead to decreased bone density in both female and male subjects.
>
> Tissue culture experiments indicate that approximately one-third of human breast cancers are prolactin dependent *in vitro*, a factor of potential importance if the prescription of these drugs is contemplated in a patient with previously detected breast cancer. An increase in pituitary gland, mammary gland, and pancreatic islet cell neoplasmia (mammary adenocarcinomas, pituitary and pancreatic adenomas) was observed in the risperidone carcinogenicity studies conducted in mice and rate (see PRECAUTIONS – Carcinogenesis, Mutagenesis, Impairment of Fertility). Neither clinical studies not epidemiologic studies conducted to date have shown an association between chronic administration of this class of drugs and tumorigenesis in humans; the available evidence is considered too limited to be conclusive at this time.[11]

Under the "Other Events Observed During the Premarketing Evaluation of Risperdal®" section in the October 2006 label, there is a sub-section entitled "Endocrine Disorders" which states:

> Endocrine Disorders
> *Rare*: gynecomastia, male breast pain, antidiuretic hormone disorder.[12]

[10] Hilgendorff Cert., Exhibit D at 12-13.
[11] Id. at 15-16.
[12] Id. at 37.

III. Mr. Apel's Prescriber and Prescription History

A. Dr. Sirajuddin Ismail, M.D.

On March 3, 2007, Mr. Apel was involuntarily admitted to the Kimball Medical Center Short Term Care Psychiatric Unit.[13] Dr. Ismail performed a psychiatric assessment and prescribed a course of medications for Mr. Apel upon his admission. On March 6. 2007, Dr. Ismail began treating Mr. Apel with Risperdal®.[14]

i. Dr. Ismail's Background and Knowledge of Risperdal®

Dr. Ismail is Board certified in psychiatry and neurology, and also serves as an attending physician and medical director at Saint Barnabas Behavioral Health Center.[15] Dr. Ismail first started prescribing Risperdal® to patients when he was in his residency program.[16] As a part of his practice, Dr. Ismail relied on several different sources in developing his knowledge of psychotropic drugs, including Risperdal®:

> Q: Doctor, in terms of your knowledge about Risperdal and other psychotropic medications that you prescribed in 2007. would it be correct to say you generally learned about the risks, benefits and indications from your education, your training, your background and your review of published literature?
> Mr. McAlindin: Objection to form.
> A: Yes.
> Q: Breaking that down, is it correct that one source you relied on in 2007 was your medical education?
> Mr. McAlindin: Objection to form.
> A: Yes.
> Q: And is it true that another source of information you relied on in 2007 was discussions with colleagues?
> Mr. McAlindin: I object to form
> A: Yes.
> Q: And is it true that another source of information you would have relied on in 2007 was your clinical experience?

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[13] Def. Brief at 4.
[14] Id. at 4.
[15] Id. at 6.
[16] Id. at 6. See also Deposition transcript of Dr.Sirajuddin Ismail dated April 28, 2014 (hereinafter "Ismail Dep.") at 25:24 – 26:4.

Mr. McAlindin: I object to form.
A: Yes.
Q: And yet one more source of information you would have relied on in 2007 was published literature, correct?
Mr. McAlindin: I object to form.
A: Yes.
Q: Doctor, in 2007 did you have a hard copy of the Physician's Desk Reference available to you?
A: Yes. It is available.
Q: Did you use the Physician's Desk Reference in 2007?
A: Like I usually use the PDR, that is known as, [sic] and also the Epocrates...
Q: And, Doctor, those are both sources you had available to you in 2007?
A: Yes.

....

Q: Doctor, is it correct that all the sources we've just gone through were available to you and you relied on them in making prescribing decisions about various psychotropic medications including Risperdal in 2007?
Mr. McAlindin: Objection to form.
A: Yes.
Q: And in making the decision to prescribe Risperdal to Mr. Apel in 2007, you would have considered and relied upon all available sources of information, correct?
Mr. McAlindin: Objection to form.
A: Yes.[17]

At the time Dr. Ismail prescribed Risperdal® to Mr. Apel, Dr. Ismail was aware of the potential risks and side effects of Risperdal®. During his deposition, Dr. Ismail testified regarding the warnings that he provided to Mr. Apel. For example, when Dr. Ismail first prescribed Risperdal® to Mr. Apel, Dr. Ismail specifically noted in Mr. Apel's chart that Mr. Apel was warned about the possible involuntary movements he could experience as a side effect of taking Risperdal®:

Q: The next sentence says, "Following additional discussion, including possible side effects of involuntary repetitive movements of the mouth, lips, jaw and tongue, as well as tremors and to-and-fro movement, a small dose of Risperdal as well as Klonopin were then prescribed on March 6."
A: Yes.[18]

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[17] Ismail Dep. at 28:18-31:9.
[18] Ismail Dep. at 34:21-35:3.

In March of 2007, it was part of Dr. Ismail's practice to warn patients, including Mr. Apel, about the potential side effects associated with Risperdal® usage:

> Q: And in March of 2007, what did you tell patients with respect to the risks associated with the use of the medication Risperdal?
> A: Generally I tell them that it comes with the side effect of that it can increase the weight, increase the appetite. And these are some of the side effects. And then some of the other side effects that are on long-term that it can lead to tardive dyskinesia, akathisia, hyperprolactinemia.
> Q: Other than mentioning it can lead to tardive dyskinesia, did you explain what that is?
> A: Yes.
> Q: How did you explain to patients using Risperdal in March of 2007 what tardive dyskinesia is?
> A: These are some of the oral abnormal movements, lip smacking, thrusting of the tongue and some of the involuntary movements of the shoulder, and to-and-fro movements.
> Q: Anything else with respect to the description of tardive dyskinesia?
> A: And inability to express, inability to talk and difficulty in – like when a person would talk, he would spit things from his mouth.
> Q: Those are things that you told Mr. Apel.
> A: In general, yeah.
> Q: You think you told that to Mr. Apel?
> A: Yes.[19]

Additionally, during his deposition, Dr. Ismail was shown the October 2006 Risperdal® package insert and asked a series of questions about Risperdal's® side effects at the time Dr. Ismail prescribed the medication to Mr. Apel in March 2007. Dr. Ismail responded to each question affirmatively, indicating his knowledge of the various side effects, specifically tardive dyskinesia and hyperprolactinemia. Dr. Ismail testified that he was aware that Risperdal® can cause tardive dyskinesia:

> Q: If you would turn to page 12, Doctor, does that page contain the beginning of the warning section?
> A: Yes.
> ....

[19] Ismail Dep. at 118:16 – 119:23.

Q: And at the bottom of this page in the Warnings section do you see the word "tardive dyskinesia"?
A: Yes.

...

Q: At the top there it says, "A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs." Did I read that correctly?
A: Yes.
Q: Is that information that you were aware of in March 2007?
A: Yes.[20]

Dr. Ismail was questioned at his deposition on almost every sentence of the "Tardive Dyskinesia" section of the October 2006 Risperdal® label and asked whether he knew of the specific side effects. When asked whether he was aware of the side effect in March 2007, when he prescribed Risperdal® to Mr. Apel, Dr. Ismail unequivocally answered "yes" each time.[21]

Dr. Ismail also gave deposition testimony as to his knowledge of hyperprolactinemia as a potential side effect of Risperdal® usage:

Q: If you would please turn to page 16. And actually if you go back to 14. At the bottom in bold do you see where it says Precautions?
A: Yes.
Q: Would you tell us generally what type of information do you find in the Precaution section of a package insert?
A: These are some of the side effects, general side effects, that person should be very cautious [sic] while taking this medication.
Q: And if you would not turn to 15. Near the bottom do you see the bold word Hyperprolactinemia?
A: Uh-hum, yes.
Q: Do you agree with me looking at this document that hyperprolactinemia is contained within the Precautions section here?
A: Yes

...

Q: Looking at the line below that, "As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration." Did I read that correctly?

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[20] Ismail Dep. at 83:5-8, 83:17-19; 84:6-17.
[21] See generally Ismail Dep. 83:1-86:20.

A: Yes.
Q: Is that information you were aware of in March of 2007?
A: Yes.
Q: Is that information you would have shared with Mr. Apel in March 2007?
Mr. McAlindin: I object to form.
A: Yes.

....

Q: Going down to the next paragraph, the third sentence, it says, "Galactorrhea, amenorrhea, gynecomastia and impotence have been reported in patients receiving prolactin-elevating compounds." Did I read that correctly?
A: Yes.
Q: Is that information you were aware of in March 2007?
A: Yes.[22]

Lastly, Dr. Ismail testified unequivocally that he would still prescribe Risperdal® for Mr. Apel today:

Q: Do you hold the same opinion that Risperdal was indicated for Mr. Apel in 2007, to a reasonable degree of medical probability today?
A: Yes.
Q: Was it your opinion, to a reasonable degree of medical probability in 2007, that the benefits of Risperdal for Mr. Apel outweighed the potential risks?
A: Yes.
Q: And do you hold the same opinion that the benefits of Risperdal for Mr. Apel outweighed the potential risks in 2007 to a reasonable degree of medical probability today?
A: Yes.
Q: Knowing what you know today, would you make the same decision to prescribe Risperdal to Mr. Apel?
Ms. Klubenspies: Note my objection. You can answer.

A: Like if this medication is helping, then I would prescribe.[23]

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[22] Ismail Dep. at 86:25-87:18; 88:7-15; 89:8-17.

[23] Ismail Dep. at 106:23-107:18. Later in the deposition, Plaintiffs' counsel asked Dr. Ismail whether he would still prescribe Risperdal® to Mr. Apel. Ismail Dep. at 142:8-9. Dr. Ismail answered in the negative because Mr. Apel had developed certain side effects. Id. at 142:12-14. However, Dr. Ismail was unwaivering in his deposition testimony that the benefits of Risperdal® outweighed the drug's risks as Mr. Apel's mental condition improved markedly when Mr. Apel was prescribed the drug.

ii. Promotion of Risperdal® to Dr. Ismail

According to Dr. Ismail's deposition testimony, any promotional materials that he received from the manufacturer of Risperdal®, were minimal:

> Q: Were you ever provided with any literature from Janssen regarding Risperdal?
> Ms. Hilgendorff: Objection.
> A: The literature about the medication?
> Q: Yes. Prior to March 2007, had you ever been provided with any literature regarding Risperdal by the manufacturer Janssen?
> A: Yes.
> Q: And what literature were you provided with?
> A: Like the literature that comes with the insert, that is more or less the same copy [that] can be found in the PDR.
> Q: How about any other literature, promotional literature or what one might call advertising literature about Risperdal form Janssen?
> A: I'm not aware of that....[24]

Moreover, Dr. Ismail did not recall meeting with any Janssen pharmaceutical representatives promoting Risperdal®:

> Q: Have you had, prior to March 2007, did you ever have any meetings with pharmaceutical personnel from Janssen regarding the product Risperdal?
> A: I usually don't meet them personally. They go to the pharmacy. If they have brought some speaker, we go to them.
> Q: Were there ever any seminars put on at the facility by personnel from Janssen?
> A: There may be. I'm not sure.
> Q: You can't recall any?
> A: Yes. I don't recall.[25]

B. Dr. Mahar Awad, M.D.

Dr. Awad saw Mr. Apel on March 29 and April 11, 2007 at St. Barnabas' Behavioral Health Center's Intensive Outpatient Program ("IOP").[26] Dr. Awad continued to prescribe Risperdal® to Mr. Apel.[27]

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[24] Ismail Dep. 166:22-167:15.
[25] Ismail Dep. 173:7-18.
[26] Def. Brief at 5.
[27] Id.

i. Dr. Awad's Background and Knowledge of Risperdal®

Dr. Awad is "a practicing psychiatrist who is Board certified in psychiatry and neurology, as well as addiction medicine."[28] He learned about Risperdal® as early as 1996.[29] In 2007, at the time he was treating Mr. Apel, Dr. Awad relied on several different sources in developing his knowledge about Risperdal® and other psychotropic medications:

> Q: In terms of your knowledge about Risperdal and other psychotropic medications you prescribed in 2007, would it be correct to say you generally learned about the risks, benefits, indications and contraindications from your education, your training your background and your review of published literature?
> A: Yes.
> Q: So then it's correct to say that one source you relied upon in 2007 was your medical education, correct?
> A: Yes.
> Q: And it's correct that another source of information you relied on was discussions with colleagues, correct?
> A: Yes.
> Q: And another source of information you relied on in 2007 was your own clinical experience, correct?
> A: Correct.
> Q: And yet another source of information you relied on in 2007 would be your review of published literature, correct?
> A: Correct.
>
> ....
>
> Q: What would you say was your primary source of information about drugs you needed to prescribe in 2006 and 2007?
> A: Like I said, my education background, conferences. Sometimes I looked in the page insert which is part of the PDR. Collectively it's all the information I learned.
> Q: In making the decision to prescribe Risperdal to Mr. Apel in 2007, you would have considered and relied upon all the available sources of information to you, correct?
> A: Yes.[30]

At the time Dr. Awad prescribed Risperdal® to Mr. Apel, Dr. Awad was aware of the potential risks and side effects of Risperdal®:

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[28] Id. at 9.
[29] Deposition transcript of Dr. Mahar Awad dated April 2, 2014 (hereinafter "Awad Dep.") at 38:4-8.
[30] Awad Dep. at 41:3-25, 42:1, 43:7-18.

Q: In 2007 when you continued the prescription for Risperdal to Mr. Apel, were you aware that tardive dyskinesia was a potential risk or side effect associated with Risperdal?
A: Yes.
Q: In 2007 when you prescribed Risperdal to Mr. Apel, were you aware that akathisia was a potential risk or side effect associated with Risperdal?
A: Yes.
Q: In 2007 when you prescribed Risperdal to Mr. Apel, were you aware that development of gynecomastia was a potential risk for side effect associated with Risperdal?
A: Yes.[31]

At his deposition, Dr. Awad testified about the warnings that he provided to Mr. Apel:

Q: What were the potential risks and side effects that you would have told Mr. Apel in March of 2007 about Risperdal?
Mr. McAfindin: I object to the form:
Q: You can go ahead.
A: I always discuss side effects about antipsychotics with my patients. I tell them about short-term side effects of medications and long-term side effect of medication. I always say that short-term side effects of medication is called neuroleptic malignant syndrome. So if he ever developed fever or rigidity you have to go to the hospital because this is a serious condition, but it is very rare. *I tell them about long-term side effects of medication including tardive dyskinesia, and, in fact, I mimic the tardive dyskinesia for them to understand, and I tell them it's involuntary movement.* It can happen anywhere in the body. Sometimes it does not get better when you stop the medication and usually it's some long-term side effect. It can interfere with your speech because you see your tongue moving by itself sometimes....And *the next bullet is prolactin elevation.* I tell them prolactin is a normal hormone that is created in the body. Sometimes a medication raises that level in the body, and if that happens it can cause sexual side effects like weak erection, *enlarged* breasts in make or it can cause women to lose their period or start lactating.
Q: I apologize if I missed this. Would you have specifically discussed the risk of tardive dyskinesia with Mr. Apel?
A: Yes.
Q: As well as other potential movement disorders?
A: Correct. The Parkinsonian also, Parkinsonian side effects, the tremors, I always discuss with the patient.[32]

[emphasis added]

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[31] Awad Dep. at 69:16-25, 70:1-5.
[32] Awad Dep. at 34:7-35:6; 35:12-36:3.

Dr. Awad affirmed his communications to Mr. Apel regarding Risperdal's® side effects as of 2007 more than once during his deposition testimony:

> Q: And would the warnings or the – I don't want to say warnings, but specific with Risperdal, what would you have discussed with Mr. Apel?
> ....
>
> A: I always discuss those side effects in general all the antipsychotics including the Risperdal. And I begin by saying why I'm giving the Risperdal for and we agreed upon that he had psychosis in the inpatient unit and the medication helped the psychotic part of it. And then I go to the side effects. I tell him that antipsychotics, including Risperdal, have an acute, which is the short-term, side effects and long-term side effects. I tell him the short-term side effects is what we call neuroleptic malignant syndrome and usually you will get high fever, rigidity. If that ever happen, you go to the hospital right away. *I tell him about long-term side effects. I said it's tardive dyskinesia and is one of them and I explain what tardive dystocia [sic]. Sometimes I even mimic for the patient to understand...And then I discuss the issues of prolactin elevation.* And I tell them that prolactin is a normal hormone secreted in the body. Sometimes it's created by the medication, more so with the Risperdal. *And the side effects of elevated prolactin, even though it is rare, but it can be enlarged breasts in male*, sexual dysfunction like weak erection in male, and stopping of the period and lactation in female.[33]
>
> [emphasis added]

Additionally, during his deposition, Dr. Awad was shown the October 2006 Risperdal® label and asked a series of questions about his knowledge of Risperdal's® side effects at the time he prescribed the medication to Mr. Apel. Dr. Awad responded to each question affirmatively, indicating his knowledge of the various side effects, specifically tardive dyskinesia and hyperprolactinemia. Dr. Awad testified that he was aware that Risperdal® can cause tardive dyskinesia:

> Q: Does the October 2006 insert for Risperdal that we're looking at contain the statement, "A syndrome of potentially irreversible, involuntary dyskinetic movements may develop in patients treated with antipsychotic drugs?
> A: Yes.
> Q: Is that information you were aware of in March 2007?
> A: I was.

[33] Awad Dep. at 169:4-7, 169:15-25; 170:1-7, 170:11-20.

Q: Going down to the fourth sentence in that paragraph, does it say, "Whether antipsychotic drug products differ in their potential to cause tardive dyskinesia is unknown?"

...

A: Yes. You read it correctly.
Q: Is that information you were aware of in March 2007?
A: Yes.[34]

At his deposition, Dr. Awad was queried about almost every sentence of the "Tardive Dyskinesia" section of the October 2006 Risperdal® label and asked whether he knew about a specific aspect of each side effect. When asked whether he was aware of the side effect at the time he prescribed Risperdal® to Mr. Apel, Dr. Awad unequivocally answered "yes" each time.[35]

Dr. Awad's deposition testimony also made clear that he knew hyperprolactinemia was a potential side effect of Risperdal® usage:

Q: Do you agree that this October 2006 version of the Risperdal package insert contains the statement, "As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration"?
A: Yes.
Q: Is that information that you were aware of in March of 2007?
A: Yes
Q: Next sentence, do you agree that it states, "Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents?"
A: Yes. I'm aware.
Q: Is that information that you were aware of in March of 2007.
A: Yes.
Q: Is the information contained in the two sentences I just read information that you would have generally discussed with Mr. Apel in March of 2007?
Mr. McAlindin: I object to form.
A: Yes.
Q: Yes, it is?
A: Yes.
Q: Going down to the next paragraph in the third sentence – we're still on page 15 – the paragraph that starts, "Hyperprolactinemia may suppress," in the third sentence do you agree that it says, "Galactorrhea, amenorrhea, gynecomastia and impotence have been reported in patients received prolactin-elevating compounds?"
A: Yes.

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[34] Awad Dep. at 74:20-25; 75:1-9, 75:18-21.
[35] See generally Awad Dep. at 74:20-76:19.

Q: And is that information you were aware of in March 2007?
A: Yes.
Q: And would you have generally discussed with Mr. Apel in March of 2007 that gynecomastia is something that could have been reported in patients taking Risperdal?
Mr. McAlindin: I object to form.
A: Yes, I did.[36]

Lastly, Dr. Awad confirmed that he would still prescribe Risperdal® for Mr. Apel today:

Q: Do you believe you had sufficient information in March 2007 to make an appropriate risk/benefit analysis regarding Mr. Apel's use of Risperdal?
A: Yes.
Q: Was it your opinion, to a reasonable degree of medical probability in 2007, that Risperdal was indicated for Mr. Apel.
Mr. McAlindin: I object to form.
A: Can you rephrase the question?
Q: Yes. In March 2007, when you continued the prescription of Risperdal for Mr. Apel, was it your opinion, to a reasonable degree of medical certainty, that it was indicated for him?
Mr. McAlindin: Objection to form.
A: Are you referring to FDA indications?
Q: No. Just—
A: Or clinical
Q: Clinical.
A: Yes.
Q: Clinically indicated?
A: Yes.
Q: Do you hold that same opinion today that in March of 2007 Risperdal was clinically indicated for Mr. Apel?
A: Absolutely.
Q: And why do you say absolutely?
A: Because the patient was doing very well on the medication and showed 360-degree turnaround in a short period of time without any side effects.[37]

ii. Promotion of Risperdal® to Dr. Awad

According to Dr. Awad's deposition testimony, any promotional materials that he received from the manufacturer of Risperdal® were purely educational:

Q: Did you ever receive any literature from Janssen that you perceived as an effort to encourage you to prescribe Risperdal to any of your patients.

[36] Awad Dep. at 79:1-80:19.
[37] Id. at 84:24-86:6.

...

A: You alluding that anybody coerced me to prescribe Risperdal?
Q: No. I'm not saying coerced. I think at the end of the day, you would not prescribe a medication as a result of coercion. I think that would be a fair statement. Would you agree with that?
A: Yes.
Q: But did you receive literature from Janssen that you perceived to encourage you to prescribe it?
A: I think all the literature I received was pure [sic] educational.
Q: And none of it was what one might consider marketing material?
A: What you call marketing material?
Q: Marketing material that advised of the benefits of a medication and suggested that it may be a better product than other antipsychotics?
Ms. Hilgendorff: Objection. States facts not in evidence.
A: Well, every representative that come to my office and talk about medication will talk how good his product is.
Q: You would have people, representatives, for different pharmaceutical companies come and try to sell you on particular products. Is that fair to say?
A: Educate me about particular products.[38]

At times, Janssen representatives provided Dr. Awad with educational materials about Risperdal®:

Q: Do you have any literature other than what one might describe as the package insert for Risperdal regarding that product?

...

A: Well, I have the articles from magazines and journals. Not necessarily I'm keeping them. It's tons and tons of them.
Q: Do you have any literature that was provided from the manufacturer Janssen with respect to Risperdal?
A: Again, articles coming from journals, yes. Sometimes a representative come and say, "This article was in the American Journal of Psychiatry. And they hand it to me and I take it, I read it.
Q: Do you have a specific recollection of being provided with such articles from journals regarding the product Risperdal?
A: I'm sure there is, but I don't remember which article and when.[39]

Additionally, Dr. Awad was never offered incentives by any Janssen representatives to prescribe Risperdal®:

[38] Awad Dep. at 133:2-5, 133:9-25; 134:1-14.
[39] Awad Dep. at 136:10-12, 137:12-138:2.

Q: Did they ever offer to entertain you in any way, tickets to events, dinners, anything of that sort?
A: Never.[40]

C. Dr. Surinderjeet Sandhu, M.D.

As of May 9, 2007, when Mr. Apel was discharged from St. Barnabas' Behavioral Health Center's Intensive Outpatient Program, Mr. Apel began treating with Dr. Sandhu. Dr. Sandhu "continued Mr. Apel's Risperdal prescription over the following nine to ten months."[41]

i. Dr. Sandhu's Background and Knowledge of Risperdal®

Dr. Sandhu is "a practicing psychiatrist who is Board certified in psychiatry and neurology, as well as addiction medicine."[42] Dr. Sandhu "first prescribed Risperdal® when it was introduced into the market."[43] Dr. Sandhu relied on several different sources in developing his knowledge of Risperdal® and other psychotropic drugs:

Q: And in terms of your knowledge about Risperdal and other psychotropic medications you prescribed in 2007, would it be correct to say you generally learned about the risks, benefits, indications and contraindications from your education, your training, your background and your review of published literature?
A: Correct.
Mr. McAlindin: I object to form.
Q: Yes?
A: Correct.
Q: So breaking that down, it's correct that one source you relied on in 2007 was your medical education?
A: Correct.
Q: And another source you relied on in 2007 was discussions with your colleagues?
A: Correct.
Q: And another source you relied on was your own clinical experience?
A: Correct.
Q: And yet one other source you relied on in 2007 was your review of published literature?
A: Correct.

....

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[40] Awad Dep. at 135:13-16.
[41] Plaintiffs' Brief in Opposition to the Motion for Summary Judgment filed by Defendants ("Pl. Brief") at 3.
[42] Def. Brief at 12.
[43] Id.

Q: Is it correct that all of the sources we've just discussed, that you would have relied on them in making prescribing decisions about various psychotropic medication including Risperdal in 2007?
A: Correct.
Q: And in making the decision to prescribe Risperdal for Mr. Apel in 2007, you would have considered and relied upon all the available sources of information, correct?
A: Correct.[44]

At the time Dr. Sandhu prescribed Risperdal® to Mr. Apel, Dr. Sandhu was aware of the potential risks and side effects of Risperdal®:

Q: Isn't it true that in 2007 you were aware of a reported association between Risperdal and tardive dyskinesia?
A: Yes.
Q: Isn't it also true that in 2007 you were aware of a reported association between Risperdal and gynecomastia?
A: Yes.[45]

Additionally, at his deposition, Dr. Sandhu testified about the warnings he provided to Mr. Apel. For example, when Dr. Sandhu first prescribed Risperdal® to Mr. Apel, Dr. Sandhu specifically warned about tardive dyskinesia and gynecomastia:

Q: Okay. And after you discussed the risks associated with Lamictal, did you then discuss the risks associated with the use of Risperdal?
A: Yes.
Q: And do you recall that discussion?
A: Yes.
Q: What did you tell Mr. Apel in that regard?
A: That I told him that you had received this medication from the hospital. They have given it. I think you have improved on it. And there are side effects for long-term use of this medication. And they are especially tardive dyskinesia. There is chances of metabolic problems, increased cholesterol, diabetes. And I told him that your weight is already on the higher side, so there are more chances of you having these problems.
Q: Which ones?
A: Cholesterol and diabetes. And also I told him about immediate side effects like sometimes neuromalignant syndrome. Then sometimes akathisia or sometimes EPS symptoms. Then I told him about gynecomastia, that that can happen too.

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[44] Deposition Transcript of Dr. Surinderjeet Sandhu dated April 17, 2014 (hereinafter "Sandhu Dep.") at 29:22-30:21; 31:22-32:7.
[45] Sandhu Dep. at 105:10-17.

> Q: What was the specific nature of your warning of the risk of tardive dyskinesia?
> A: I told him it's abnormal movements and this can be irreversible and it happens due to long-term use of antipsychotics and it's more common with the higher age, and in your case that, because of your symptoms, it's necessary that you should be on antipsychotics, small doses. And also he told me that he had taken Risperdal many times before, and this is only antipsychotic which helps him the best.[46]

At his deposition, Dr. Sandhu was shown the October 2006 Risperdal® label and asked a series of questions about his knowledge of Risperdal's® side effects at the time he prescribed the medication to Mr. Apel in March 2007. Dr. Sandhu responded to each question affirmatively, indicating his knowledge of the various side effects in 2007, specifically tardive dyskinesia and hyperprolactinemia. First, Dr. Sandhu testified that he was aware that Risperdal® can cause tardive dyskinesia:

> Q: So. What I've handed you is a copy of the Risperdal package insert that went into effect as of October 2006. Do you agree that's the date we have on there?
> A: Yes.
>
> ...
>
> Q: Down at the bottom of the page, do you see the bolded words Tardive Dyskinesia?
> A: Yes, I do.
> Q: And do you agree that that is in the warning section?
> A: Yes.
> Q: If you flip to the next page, page 13, the very first since on that page says, "A syndrome of potentially irreversible, involuntary, dyskinetic movements may develop in patients treated with antipsychotic drugs." Did I read that correctly?
> A: Yes.
> Q: Doctor, is that information that you were aware of in May of 2007?
> A: Yes, I was.
> Q: And is that information that you would have shared with Mr. Apel when you prescribed Risperdal for him in May of 2007?
> A: Yes.[47]

During his deposition, Dr. Sandhu was asked about almost every sentence of the "Tardive Dyskinesia" section of the Risperdal® label and whether he knew of each side effect. When asked

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[46] Sandhu Dep. at 159:18-161:4.
[47] Sandhu Dep. at 35:2-6, 35:23-25; 36:1-17.

whether he was aware of the potential side effect in May 2007, when he began prescribing Risperdal® to Mr. Apel, Dr. Sandhu unequivocally answered "yes" each time.[48]

Dr. Sandhu also made clear during his deposition that, at the time he prescribed Risperdal® to Mr. Apel, he knew of hyperprolactinemia as a potential side effect of Risperdal® usage:

> Q: If you would turn to page 15. Down near the bottom you see a section entitled Hyperprolactinemia?
> A: Yes.
> Q: And do you agree that that is contained within the precaution section of this label?
> A: Yes.
> Q: Are you familiar with hyperprolactinemia?
> A: Yes. I am.
>
> ....
>
> Q: Doctor, if you look at the first sentence under the word Hyperprolactinemia, it says, "As with other drugs that antagonize dopamine D2 receptors, risperidone elevates prolactin levels and the elevation persists during chronic administration." Did I read that correctly?
> A: Yes.
> Q: Is that information you were aware of in 2007?
> A: Yes, I was.
> Q: Is that information you would have shared generally with Mr. Apel in 2007?
> Mr. McAlindin: I object to form.
> A: Yes.
> Q: The next sentence says, "Risperidone is associated with higher levels of prolactin elevation than other antipsychotic agents." Did I read that correctly?
> A: Yes.
> Q: And is that information you were aware of in 2007?
> A: Yes.
> Q: And is that information you would have shared with Mr. Apel in 2007?
> A: Yes.
> Q: Going to the next paragraph in the third sentences it says, "Galactorrhea, amenorrhea, gynecomastia and impotence have been reported in patients receiving prolactin-elevating compounds." Did I read that correctly?
> A: Correct.
> Q: Is that information that you were aware of in May of 2007?
> A: Correct.
> Q: Would you have shared the relevant portions of that sentence with Mr. Apel in 2007?
> Mr. McAlindin: I object to form.

[48] See generally Sandhu Dep. at 35:2-38:25.

A: Yes.[49]

Lastly, Dr. Sandhu testified that he would still prescribe Risperdal® to Mr. Apel today:

> Q: Was it your opinion, to a reasonable degree of medical probability, that in 2007 Risperdal was indicated for Mr. Apel?
> Mr. McAlindin: Objection to form.
> A: Yes.
> Q: Do you still hold that opinion today?
> Mr. McAlindin: Objection to form.
> A: Yes.
> Q: Was it your opinion, to a reasonable degree of medical probability, in 2007 and 2008 that the benefits of Risperdal for Mr. Apel outweighed the potential risks?
> Mr. McAlindin: Objection to form.
> A: Yes.
> Q: Do you hold that same opinion today?
> A: Yes.
> Q: Knowing what you know now, would you make the same decision to continue the prescription of Risperdal for Mr. Apel?
> A: Yes.
> ....
>
> Q: Do you continue to use Risperdal in your practice today?
> A: Yes, I do.[50]

ii. Promotion of Risperdal® to Dr. Sandhu

According to Dr. Sandhu's deposition testimony, he did not review any literature that the manufacturer of Risperdal® may have sent to him:

> Q: In your practice, whether it with Preferred Behavioral or the Ann Klein Forensic Center or even the Ocean Correctional Facility, do you receive literature from any pharmaceutical manufacturers regarding certain products?
> A: Yes.
> Q: Have you received literature regarding Risperdal?
> A: We receive letters all the time from all the pharmaceutical companies.
> Q: Do you keep files on particular—
> A: No.
> Q: Just throw it in the circular file, garbage?
> A: Garbage. Because they have to send it. Every day I get like 10 letters from different pharmaceutical companies whenever the medication comes or they just want to keep warning with the follow-up letters. So you can't read all them.[51] [sic]

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[49] Sandhu Dep. at 39:16-40:1; 40:11-41:25.
[50] Sandhu Dep. at 104:13-105:9, 109:18-20.
[51] Sandhu Dep. at 213:4-24.

Additionally, any visits Dr. Sandhu had from Janssen representatives were minimal:

> Q: Do you receive visits from pharmaceutical sales personnel from time to time?
> A: Yes, we do.
> Q: Have you ever received any such visit from a representative of the manufacturer of Risperdal?
> A: Yes.
> Q: Who are those representatives? Do you recall any by name?
> A: Not at all. It has been many years.
> Q: Has that been something that has occurred with frequency over the course of your career?
> A: No.
> Q: Do you have any recollection of any of those visits where this product Risperdal was discussed?
> A: I don't recall.
> Q: Has there ever been any sales personnel who have suggested to you that Risperdal is more effective than any of the other second generation antipsychotics?
> Ms. Hilgendorff: Objection.
> A: No.
> Q: Have there been any representations that it's less effective than any of the other antipsychotics?
> A: No. We make the decision on our patients and everybody tells us their product is better than other one, but, again, ultimate decision is by me.
> Q: You go by what suits your patients best?
> A: Suits my patient, yes.[52]

IV. Motions for Summary Judgment

A. Defendants' Motion

Under New Jersey law, Defendants seek summary judgment on Plaintiffs' failure to warn claims based on two theories. First, that Plaintiffs' failure to warn claims should be dismissed pursuant to the learned intermediary doctrine. Defendants argue that Risperdal's® "package insert included warnings about the risks of TD [tardive dyskinesia] and gynecomastia, and...Drs. Ismail, Awad and Sandhu were aware of the risks from multiple sources."[53] As such, Defendants believe that "[t]his is a case in which different or additional warnings would not have altered their [the

[52] Sandhu Dep. 213:25-215:9.
[53] Def. Brief at 19.

doctors'] prescribing decisions."[54] Second, Defendants argue that the Risperdal® label is adequate as a matter of law. Defendants contend that the warnings for tardive dyskinesia and gynecomastia "were 'accurate, clear and unambiguous,' and satisfied the three-step analysis adopted in New Jersey" to determine the adequacy of a label's warning.[55] Defendants also allege that Plaintiffs' remaining claims are subsumed by New Jersey's Products Liability Act, N.J.S.A. § 2A:58C-1 to 11.

B. Plaintiffs' Opposition

Plaintiffs, in their belatedly filed opposition to Defendants' summary judgment motion, assert four counter arguments. First, Plaintiffs argue that the learned intermediary doctrine does not apply because of the "exception to the learned intermediary doctrine involving what has been termed 'direct-to-consumer' (DTC) advertising."[56] Second, Plaintiffs allege that the warnings in the Risperdal® label, at the time Mr. Apel was prescribed the drug, were not adequate as a matter of law.[57] Third, Plaintiffs argue for application of a heeding presumption in this case.[58] Lastly, Plaintiffs contend that there are genuine issues of material fact that preclude summary judgment in this matter.[59]

V. Summary Judgment Standard

Under New Jersey law, summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories and admission on file, together with the affidavits, if any, show that

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[54] Id. at 20.
[55] Id. at 23.
[56] Pl. Brief at 5.
[57] Id. at 11-12.
[58] Id. at 12.
[59] Id. at 13-14. The court notes that Plaintiffs' point heading for this section states, "Summary judgment is proper here as there are no genuine issue of material fact and the defendant is entitled to summary judgment as a matter of law." Id. at 13. It is evident that Plaintiffs' counsel never sought summary judgment, and that the heading was written in error.

there is no genuine issue as to any material fact challenged and that the moving party is entitled to a judgment or order as a matter of law." R. 4:46-2(c). The determination of whether genuine issues of material fact exist requires the court to "consider whether the competent evidential materials presented, when viewed in the light most favorable to the non-moving party, are sufficient to permit a rational fact-finder to resolve the alleged disputed issue in favor of the non-moving party." Brill v. Guardian Life Ins. Co., 142 N.J. 520, 540. It is not the court's function to "weigh the evidence and determine the truth of the matter but [rather] to determine whether there is a genuine issue for trial." Id.

VI. Legal Standard and Analysis

A. Adequacy of the Label As a Matter of Law

In New Jersey, all products liability actions are governed by the Products Liability Act ("PLA"), N.J.S.A. § 2A:58C-1 to 11; see also Banner v. Hoffman-La Roche, Inc. 383 N.J. Super. 364, 375, certif. denied, 190 N.J. 292 (2007). The PLA covers "any claim or action brought by a claimant for harm caused by a product, irrespective of the theory underlying the claim, except actions for harm caused by breach of an express warranty." N.J.S.A. § 2A-58C-1(b)(3). Under the statute,

> A manufacturer or seller of a product shall be liable in a product liability action only if the claimant proves by a preponderance of the evidence that the product causing the harm was not reasonably fit, suitable, or safe for its intended purpose because it: a. deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae, or b. failed to contain adequate warnings or instructions, or c. was designed in a defective manner.
>
> [N.J.S.A. §2A:58C-2; Banner, supra, 383 N.J. Super. at 375.]

A manufacturer or seller of a product may not be liable under the PLA if an adequate warning was given:

> In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction. . . . An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, *or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician.* [emphasis added]
>
> [N.J.S.A. § 2A:58C-4]

As stated in the statute, in the case of prescription drugs, the warning must be directed toward the prescribing physician. This is known as the "learned intermediary" doctrine. Under this doctrine, "a pharmaceutical manufacturer generally fulfills its duty to warn the ultimate user of its prescription...when it supplies physicians with adequate information about a drug's dangerous propensities." Banner, supra, 383 N.J. Super. at 375; Niemiera v. Schneider, 114 N.J. 550, 559. As this is not a case involving DTC advertising, the warning must be directed toward the prescribing physician.[60] Thus, this court will review the adequacy of the warnings from the perspective of the physicians who prescribed Risperdal® to Mr. Apel.

Usually, "the question of whether a warning [in the context of prescription drugs] is adequate is one for a jury to resolve." Banner, supra, 383 N.J. Super. at 377. However, under appropriate circumstances—such as the case before the court today—a court may rule that a particular warning is adequate as a matter of law, particularly where the warning alerts the prescriber to the very injury alleged. Id. at 378; Spinden v. Johnson & Johnson, 177 N.J. Super. 605, 607 (App. Div. 1981). Courts have applied a three step analysis to determine whether the label for a prescription drug is adequate as a matter of law. This process was laid out by the Court of Appeals of New York, and later adopted by the New Jersey courts. Martin v. Hacker, 83 N.Y.2d

[60] See infra Part VI.B.i.

1 (1993); Banner, supra, 383 N.J. Super. 364.[61] The three step process requires (1) "an ascertainment of the seriousness of the involved risk," (2) an evaluation of the warning language "for its accuracy, clarity and relative consistency....clarity in the context of a drug warning means that the language of the warning is direct, unequivocal and sufficiently forceful to convey the risk," and (3) consideration of the warning as a whole, to determine "if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." Martin, supra, 83 N.Y.2d at 11-12. Tests adopted by other courts for determining the adequacy of a warning are based upon the same legal foundation—that the warning accurately and unambiguously warns the prescriber of the very injury at issue.

The first step in the process to determine the adequacy of a drug's label "starts with an ascertainment of the involved risk. Seriousness depends on the consequences of the side effects." (internal citations omitted) Martin, supra, 83 N.Y.2d at 11; see also Banner, supra, 383 N.J. Super. at 379. Next, "the court should evaluate the insert's language for its accuracy, clarity and relative consistency." Martin, supra, 83 N.Y.2d at 11; see also Banner, supra, 383 N.J. Super. at 379. A warning is accurate if it is "correct, fully descriptive and complete, and it must convey updated information as to all the drug's known side effects." Martin, supra, 83 N.Y.2d at 11 (internal cites omitted). Moreover, "[c]larity in the context of a drug warning means that the language of the warning is direct, unequivocal and sufficiently forceful to convey the risk." Id. It is important that the label is not inconsistent. If not, "[a] warning that is otherwise clear may be obscured by inconsistencies or contradictory statements made in different sections of the package insert

[61] Defendants, in their moving papers, cite to Bailey v. Wyeth, Inc., 424 N.J. Super. 278 (Law Div. 2008), aff'd, Deboard v. Wyeth, Inc., 422 N.J. Super. 360 (App. Div. 2011), for the proposition that "there is a rebuttable presumption that FDA-approved warnings are adequate." Def. Brief at 23. The Bailey court undertook an extensive analysis of the history of the drug at issue in that litigation. In this case, the court was not presented with the detailed information provided to the court in Bailey. Thus, this court declines to apply the Bailey court's findings and conclusions to the facts in this case.

regarding the same side effect or from language in a later section that dilutes the intensity of a caveat made in an earlier section." Id. Lastly, the warning must be considered in its entirety. Though "a meticulous examination and parsing of individual sentences in the insert may arguably reveal differing nuances in meaning or variations in emphasis as to the seriousness of a side effect, any resulting vagueness may be overcome if, when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." Id.; Banner, supra, 383 N.J. Super. at 379.

Applying the above standard, the October 2006 Risperdal® label, which was in effect at the time Mr. Apel was prescribed Risperdal®, is adequate as a matter of law. Admittedly, the side effects at issue in this litigation—tardive dyskinesia and gynecomastia—are serious.[62] However, these side effects are not as serious as the risk of death found in Martin, or the risk of "a profoundly malformed and disabled child," found in Banner. Therefore, the adequacy of the Risperdal® label must be evaluated based upon the less severe level of risk involved in taking the drug and less severe consequences of the drug's side effects upon the patient when compared to the level of severity for the drugs that were prescribed in the Martin and Banner cases.

Secondly, the October 2006 Risperdal® label is accurate, clear, and consistent. In terms of its accuracy, the Risperdal® label is fully descriptive and complete. The court finds no facts in the record that undermine the conclusion that the warnings as to tardive dyskinesia or gynecomastia are incorrect or incomplete.[63] Even Mr. Apel admits that there is an "overabundance" of Risperdal® information.[64] Furthermore, Plaintiffs do not allege that the Risperdal® label did not

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[62] For example, "[t]ardive dyskinesia is characterized by repetitive, involuntary, purposeless movements. Features of the disorder may include grimacing, tongue protrusion, lip smacking, puckering and pursing, and rapid eye blinking," among others. NIH: National Institute of Neurological Disorders and Stroke. *NINDS Tardive Dyskinesia Page*, WHAT IS TARDIVE DYSKINESIA?, http://www.ninds.nih.gov/disorders/tardive/tardive.htm (last visited July 14, 2014). Gynecomastia is a different disorder, and involves "the growth of abnormally large breasts in males." U.S. National Library of Medicine, *PubMed Health*, GYNECOMASTIA, http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0003651/ (last visited July 18, 2014).

[63] See supra Part II.

[64] Pl. Brief at 11.

"convey updated information as to all the drug's known side effects." Martin, supra, 83 N.Y.2d at 11. The October 2006 Risperdal® label is also clear. "Tardive Dyskinesia," is listed specifically in the "Warnings" section and clearly describes tardive dyskinesia as, "[a] syndrome of potentially irreversible, involuntary, dyskinetic movements [that] may develop in patients treated with antipsychotic drugs."[65] The warning for gynecomastia is similarly clear. In the "Precautions" section, the October 2006 Risperdal® label states, "Galactorrhea, amenorrhea, *gynecomastia*, and impotence have been reported in patients receiving prolactin-elevating compounds."[66] (emphasis added) Finally, reading through the October 2006 Risperdal® label, there are no "inconsistencies or contradictory statements" that weaken the efficacy of the label.[67] Consequently, the October 2006 Risperdal® label is accurate, clear, and consistent in its warning of tardive dyskinesia and gynecomastia.

Lastly, the court reviewed at the October 2006 Risperdal® label in its entirety. Parts of the October 2006 Risperdal® label are clearer than others. However, the label plainly states that tardive dyskinesia may occur in patients treated with Risperdal®. And, the label plainly states that patients treated with Risperdal® have reported developing gynecomastia. Therefore, the court finds that "when read as a whole, the warning conveys a meaning as to the consequences that is unmistakable." Martin, supra 83 N.Y.2d at 12; Banner, supra, 383 N.J. Super. at 379. Indeed,

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[65] Hilgendorff Cert., Exhibit D at 12-13.

[66] Hilgendorff Cert., Exhibit D at 15. Even though placement of the warnings for tardive dyskinesia and gynecomastia differ (one side effect is in the "Warning" section of the label and the other side effect is in the "Precautions" section of the label), the October 2006 Risperdal® label sufficiently conveys the risk of developing gynecomastia. The Risperdal® label plainly asserts, "risperidone elevates prolactin levels," and states that gynecomastia is reported in patients that receive "prolactin-elevating compounds." Id.

[67] The October 2006 Risperdal® label contains a section titled "Other Events Observed During the Premarketing Evaluation of RISPERDAL®." In the Endocrine Disorders portion of this section, gynecomastia is listed as a "rare" side effect. Hilgendorff Cert., Exhibit D at 37. This is not a "contradictory statement[] made in different sections of the package insert regarding the same side effect...that dilutes the intensity of a caveat made in an earlier section." Martin, supra, 83 N.Y.2d at 11. The statement supports that gynecomastia may occur, and does not undermine the conclusion that the warning is direct, unequivocal, and forceful.

each of Mr. Apel's prescribing physicians concurred as to the clarity, accuracy, and consistency of this label and their understanding of the significance of the risks involved with Risperdal®. The law requires that the warning given by the pharmaceutical manufacturer to the prescribing physician be accurate, but does not require a perfect warning.

The court finds that the October 2006 Risperdal® label "provides specific detailed information on the risk of [tardive dyskinesia and gynecomastia]." Martin, supra, 83 N.Y.2d at 10. Moreover, the warnings provided are "accurate, clear, and unambiguous." Banner, supra, 383 N.J. Super. at 382. Therefore, the court finds that warnings for tardive dyskinesia and gynecomastia in the October 2006 Risperdal® label are adequate as a matter of law.

B. Learned Intermediary

Even if a prescription drug's warning is inadequate, a plaintiff still "has the burden of proving that defendant's alleged inadequate warnings were a proximate cause of [his or] her injuries." Strumph v. Schering Corp., 345 N.J. Super. 309, 323 (App. Div. 1992) (Skillman, J., dissenting), rev'd on dissent 133 N.J. 33 (1993) (adopting Judge Skillman's dissent). To prove causation, Mr. Apel "must show that adequate warnings would have altered [his] doctors' decision to prescribe" Risperdal®. Id. In New Jersey, there is a long-standing "proposition that a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities." Niemiera v. Schneider, 114 N.J. 550, 559 (1989). This concept is known as the "learned intermediary doctrine." Id. Under the learned intermediary doctrine,

> a manufacturer who fails to warn the medical community of a particular risk may nonetheless be relieved of liability under the learned intermediary doctrine if the prescribing physician either did not read the warning at all, and thus did not rely on any information from the manufacturer in prescribing the product, or if the physician was aware of the risk in prescribing the product. Under these circumstances, the learned intermediary's conduct is deemed to be the superseding

> or intervening cause that breaks the chain of liability between the manufacturer and the user.
>
> [Perez v. Wyeth Laboratories, Inc., 161 N.J. 1, 58-59 (1999).]

In reviewing the facts of record in this case, the court finds that a different warning would not have changed the prescribing decisions of Drs. Ismail, Awad, or Sandhu. At no point do Plaintiffs highlight any facts or make any argument that Mr. Apel's prescribing physicians would have heeded a more adequate warning. In fact, the record before the court is replete with statements made by each of Mr. Apel's prescribing physicians that, at the time each physician prescribed Risperdal® to Mr. Apel, each physician knew that Risperdal® could potentially cause tardive dyskinesia and/or gynecomastia.

Dr. Ismail testified at his deposition that it was his practice in 2007 to warn patients about the side effects associated with Risperdal®. When specifically asked whether, in 2007, Dr. Ismail knew that Risperdal® could cause tardive dyskinesia or gynecomastia, he responded, "yes." And Dr. Ismail learned about Risperdal's® potential side effects from his education, training, background, and his review of the published literature.[68] Additionally, given what he knows today, Dr. Ismail would still prescribe Risperdal® to Mr. Apel. Thus, Dr. Ismail's deposition testimony makes clear that, at the time he prescribed Risperdal® to Mr. Apel, Dr. Ismail was aware of Risperdal's® potential side effects, and learned about Risperdal's side effects from sources other than the Risperdal® label.

As evidenced by his deposition testimony, Dr. Awad makes clear that, at the time he prescribed Risperdal® to Mr. Apel, he was also aware that the drug could cause tardive dyskinesia and/or gynecomastia. When asked whether Dr. Awad knew of those side effects arising from Risperdal® usage, Dr. Awad responded "yes." Even given his knowledge of Risperdal's® side

[68] See supra Part III.A.i.

effects, Dr. Awad would still prescribe Risperdal® to Mr. Apel today. And, as with Dr. Ismail, Dr. Awad relied on a variety of medical resources beyond the Risperdal® label—to educate himself about Risperdal's® side effects.[69]

Finally, Dr. Sandhu was similarly informed of Risperdal's® known side effects, specifically tardive dyskinesia and gynecomastia. When asked during his deposition whether Dr. Sandhu knew of those side effects at the time he prescribed Risperdal® to Mr. Apel, Dr. Sandhu testified, "yes." Like Drs. Ismail and Awad, Dr. Sandhu relied on several different sources—such as his education, training, background, and review of published literature-- to educate himself about Risperdal®. And, knowing what he knows today, Dr. Sandhu would still prescribe Risperdal® to Mr. Apel.[70]

Each prescribing physician gave deposition testimony that he was aware of Risperdal's® side effects at the time each prescribed the drug to Mr. Apel. Each prescribing physician learned of Risperdal's® potential side effects from sources other than the Risperdal® label. And each prescribing physician would still prescribe Risperdal® to Mr. Apel today. Given these facts, a different warning would not have changed the prescribing decisions made by any of Mr. Apel's physicians. Therefore, even if the October 2006 Risperdal® label was inadequate, Plaintiffs are unable to show that an alleged inadequate warning proximately caused Mr. Apel's injury because Plaintiffs cannot prove that a different warning would have changed the prescribing habits of Dr. Ismail, Dr. Awad, or Dr. Sandhu. Nor are Plaintiffs able to show that Drs. Ismail, Awad, and Sandhu were unaware of the risks associated with Risperdal® given the unequivocal deposition testimony of each prescribing physician.

i. Mr. Apel's Direct-to-Consumer Claim

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[69] See supra Part III. B.i.
[70] See supra Part. III.C.i.

In 1999, the Supreme Court of New Jersey created an exception to the learned intermediary doctrine in cases of direct to consumer ("DTC") advertising. Perez v. Wyeth Laboratories, Inc., 161 N.J. 1 (1999). In Perez, the New Jersey Supreme Court concluded that "[p]rescription drug manufacturers that market their products directly to consumers should be subject to claims by consumers if their advertising fails to provide an adequate warning of the product's dangerous propensities." Id. at 21. In a case of DTC advertising, the learned intermediary doctrine does not apply. Id.

In their opposition papers, Plaintiffs argue that the DTC exception to the learned intermediary doctrine applies in his case. The court finds no basis for this argument. Plaintiffs' papers merely restate the law and lack any facts in the record to support this argument. In fact, Mr. Apel's deposition testimony undermines his DTC claim:

> Q: Have you ever seen an advertisement for Risperdal that was not related to a Riserperdal lawsuit?
> A: Not that I know of.
> Q: So the only advertisement for Risperdal you've ever seen was related to Risperdal lawsuits, correct?
> A: I think so.
> ...
>
> Q: Before you started taking Risperdal, did you see any material at all regarding Risperdal?
> A: Not that I know of.[71]

As Mr. Apel presents no evidence to support his DTC claim, the court finds this exception to the learned intermediary doctrine inapplicable.

[71] Deposition transcript of Max Apel, Vol. 2 dated August 14, 2013 (hereinafter "Apel Dep.") at 323:19-324:1, 324:13-16.

ii. Mr. Apel's Overpromotion Claim

Some courts have adopted what is known as the "overpromotion exception" to the learned intermediary doctrine. The overpromotion exception applies in "'unusual cases' where a plaintiff can 'establish with *individualized* proof' that a drug manufacturer's excessive promotion of its product 'caused the plaintiff's physician to initiate or maintain the prescription at issue.'" Boehm v. Eli Lilly & Co., 747 F.3d 501, 508 (2014) (emphasis in original). However, New Jersey courts have not adopted the overpromotion exception, particularly in the context of claims against pharmaceutical manufacturers. Plaintiffs cite to Koruba v. Am. Honda Motor Co., Inc., 396 N.J. Super. 517 (App. Div. 2007) in support of the overpromotion exception to the learned intermediary doctrine in New Jersey. Koruba is not applicable to the issues before the court as it involves warnings to purchasers of all-terrain vehicles ("ATV"). Warnings in a consumer product situation, such as an ATV, are vastly different from the warnings to physicians for prescription drugs. In the context of prescription drugs, the warning must be given by the manufacturer to the prescribing physician because it is the prescribing physician who must be able to assess the risks/benefits of the drug product based upon a patient's medical history. The facts in Koruba are not analogous to the facts in this prescription drug case. Furthermore, no court in New Jersey has applied the overpromotion exception to the learned intermediary doctrine.

Even if New Jersey courts recognized an overpromotion exception, the facts presented in this case do not support application of the exception to Plaintiffs' case. Neither Dr. Ismail, Dr. Awad, nor Dr. Sandhu testified that they were overburdened or overwhelmed with literature from the manufacturer of Risperdal®. Additionally, all three prescribing physicians had minimal or no contact with Janssen's sales/marketing representatives.[72]

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[72] See Part III. A. ii, Part III. B. ii, and Part III. C. iii. In support of his overpromotion exception argument, Plaintiffs cite to a violation letter from the FDA to Defendants in January of 1999. Pl. Brief at 10. How a warning letter that

As New Jersey does not recognize an overpromotion exception and Plaintiffs present no evidence to support such a claim even if it did exist, the court finds this exception to the learned intermediary doctrine inapplicable.

C. Heeding Presumption as to Mr. Apel

Plaintiffs erroneously contend that the heeding presumption defeats Defendants' motion for summary judgment. The court finds that the heeding presumption is inapplicable under the circumstances of this case.

In New Jersey, "[a] plaintiff suing under a failure to warn theory must presumably establish that [he or] she would have heeded an adequate warning if one were given." Perez, supra, 161 N.J. at 28 (citations omitted). Application of the heeding presumption by New Jersey courts grew out of public policy concerns. The articulated public policy goals included: "focusing on the underlying purpose of product liability law which concentrates on a product rather than a defendant's negligence...[and] encouraging 'manufacturers to produce safer products, and to alert users of the hazards arising from the use of those products through effective warnings....'" In re Diet Drug Litigation, 384 N.J. Super., 525, 532 (Law. Div. 2005) (quoting Coffman v. Keene, 133 N.J. 581, 599 (1999)).[73] The Coffman Court held that the "use of the heeding presumption provides a powerful incentive for manufacturers to abide by their duty to provide adequate warnings." Id. Thus, a heeding presumption may be invoked where the manufacturer's warning is inadequate.

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was nearly a decade old at the time Mr. Apel was prescribed Risperdal® in 2007 is relevant to the present matter without further facts is perplexing to the court, especially given that the label in effect in 1999 differs from the label in effect in 2007.

[73] In re Diet Litigation is a Law Division case. The only higher level court citing In re Diet Litigation is McDarby v. Merck & Co., Inc. 401 N.J. Super. 10, 80 (App. Div. 2008).

The case law applying the heeding presumption recognizes the use of the presumption in appropriate circumstances. McDarby v. Merck & Co., Inc. 401 N.J. Super. 10, 80 (App. Div. 2008); In re Diet Litigation, supra, 384 N.J. Super at 542-43.[74] Both McDarby and In re Diet Drug Litigation acknowledge circumstances where the heeding presumption might not apply. In McDarby, under the circumstances of that litigation, the Appellate Division held that "the judge's use of the heeding presumption in her legal analysis and jury instructions was not legally required." McDarby, supra, 401 N.J. Super. at 82. Though the trial judge in the In re Diet Litigation case ultimately applied the heeding presumption, he noted that there are "circumstances" where the heeding presumption might not apply, such as where the need for the medication is dire and the risk is small, or where there are few alternatives to the drug selected by the prescribing physician. In re Diet Litigation, supra, 384 N.J. Super. at 542. This court agrees that there are circumstances where the heeding presumption is inapplicable, such as the circumstances presented in this litigation.

In this case, Mr. Apel was hospitalized and treated several times for his mental illness prior to his treatment in 2007 with Drs. Ismail, Awad, and Sandhu. During his earlier mental illness crises, Mr. Apel had been prescribed several different antipsychotic medications.[75] These medications were ineffective for Mr. Apel. In fact, Mr. Apel told Dr. Sandhu that Risperdal® was the only medication that had worked previously, and Mr. Apel thus specifically requested Risperdal® in 2007.[76] Additionally, Mr. Apel trusted his doctors.[77] Mr. Apel also followed the

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[74] The court notes that the McDarby court did not identify circumstances where the heeding presumption would apply. McDarby, supra, 401 N.J. Super. at 81.
[75] See PFS, Hilgendorff Cert., Exhibit B at 8.
[76] Sandhu Dep. at 32:16-24.
[77] Apel Dep. at 218:17.

advice of his doctors.[78] And Mr. Apel takes other medications, which he knows have risks and side effects.[79]

Here, Risperdal® was prescribed for a patient who had long suffered from mental illness and faced the potential of harming himself. Under such circumstances, it is the prescribing physician, familiar with the patient and the drugs used previously to treat the patient's mental illness, who was in the best position to evaluate the risks and benefits with due regard for the patient's safety. In the case of a patient suffering from mental disorders, such as Mr. Apel, the circumstances do not warrant an application of the heeding presumption. Mr. Apel's condition created dire circumstances, and Risperdal® may have been the only solution. Indeed, given the severity of his mental condition, Mr. Apel may have been unable to make an informed decision as to the use of Risperdal® at the time it was prescribed by Drs. Ismail, Awad, and Sandhu.

The adoption of the heeding presumption in New Jersey is premised upon the theory that an adequate warning was not given, and that had an adequate warning been given by the drug manufacturer to the prescribing physician, the prescribing doctor would have communicated the warning in such a way that plaintiff would have heeded the warning. Here, the prescribing physicians testified during their depositions that each doctor understood, and was aware of, the warnings associating Risperdal® with the potential side effects of tardive dyskinesia and gynecomastia. This is not a case of an inadequate warning. Instead, Plaintiffs allege that the prescribing physicians failed to provide <u>any</u> warnings to Mr. Apel regarding Risperdal®.[80]

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[78] Id. at 328:10-18.
[79] Id. at 361:3-22.
[80] Significantly, none of the physician defendants filed opposition to Defendants' motion for summary judgment. Had the doctors disputed the factual record in this case regarding their knowledge of Risperdal's® warnings, the individual doctor defendants would have filed opposing certifications and statements of disputed facts.

Plaintiffs' dispute centers on what the prescribing doctors told Mr. Apel regarding Risperdal®, not what the drug's manufacturer provided in the Risperdal® label. The heeding presumption is inapplicable as Mr. Apel's prescribing physicians testified clearly and unambiguously that each understood Risperdal's® warnings. The fact issue raised in Plaintiffs' opposition goes to whether the individual physician defendants provided Mr. Apel with information regarding the risks and benefits associated with the use of Risperdal®.[81]

Additionally, Mr. Apel's testimony that he was not warned of the potential side effects associated with the use of Risperdal® rings hollow given his overall deposition testimony. Throughout his deposition Mr. Apel's response to questions regarding conversations with his prescribing physicians was, "I don't know," "I don't recall," or "I don't remember."[82] The only thing Mr. Apel seems to recall with certainty is that his physicians did not warn him about Risperdal's® side effects. However, Mr. Apel eventually waivered in his deposition testimony on the subject:

> Q: And your testimony over these three days has been that none of those doctors, to your recollection, ever gave you any information regarding the side effects of Risperdal?
> A: *That I can remember.*[83]
> [emphasis added]

Given the testimony of Drs. Ismail, Awad, and Sandhu regarding the warnings discussed with Mr. Apel, and the circumstances presented to this court in this case, the heeding presumption is inapplicable.

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[81] Plaintiffs' claims against the individual physician defendants are not the subject of this motion for summary judgment.
[82] For example, see Apel Dep. at 385:7-388:20.
[83] Apel Dep. at 449:24-450:3.

D. Mr. Apel's Remaining Claims

The court shall grant summary judgment as to Plaintiffs' claims for negligence, breach of implied warranty, violation of the Consumer Fraud Act ("CFA") and fraud. The PLA serves as an exclusive remedy for liability arising out of product use in New Jersey. Koruba v. Am. Honda Motor Co., 396 N.J. Super. 517, 531 (App. Div. 2007). Plaintiffs' claims for negligence, breach of implied warranty, fraud and violation of the CFA are subsumed by the New Jersey's legislature's adoption of the PLA. These claims must be dismissed because the PLA does not recognize any separate cause of action independent of an alleged defective product or alleged inadequate warning. Ibid.; see also Universal Underwriters Ins. Group v. Pub. Serv. Elec. & Gas Co., 103 F.Supp.2d 744, 746 (D.N.J. 2000). Additionally, Plaintiffs' opposition brief fails to address Defendants' motion for summary judgment on these claims.

E. Loss of Consortium Claim

The court grants Defendants' motion for summary judgment as to the loss of consortium claim filed on behalf of Mrs. Joan Apel. Mrs. Apel's claim must be dismissed because it is derivative of Mr. Apel's claims, which the court is dismissing as a matter of law.

VII. Conclusion

For the reasons set forth above, Defendants' motion for summary judgment is **GRANTED** and Plaintiffs' claims, in their entirety, are dismissed with prejudice. The court shall sign an order memorializing this written decision.

JESSICA R. MAYER, J.S.C.